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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,516	08/15/2001	Katsumi Iga	074129-0488	9786

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,516	IGA ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-9,11-13,15,16,18,19,22-26,29,30,32-34 and 38* is/are pending in the application.

4a) Of the above claim(s) *7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6,8,11-13,15,16,18,19,22-26,29,30,32-34 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 4, 6-9, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2004 has been entered.

Action Summary

2. Examiner acknowledges that cancellation of claims 1-3, 5, 10, 14, 17 and 35-37. Therefore, any and all objections and rejections directed towards those claims are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 4, 6-9, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over SmithKline Beecham Co. (WO 95/06410) in view of Katz et al. (US Pat. No. 5,028,435).

SmithKline Beecham Co. ('410) discloses the use of angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane (page 28, lines 2-7 and page 29, lines 14-17). Claim 13, page 41, lines 29-33; teach where the angiotension II receptor antagonist is 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1-[(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate or pharmaceutically acceptable salt. The prior art does not disclose the skin-contacting base (i.e. adhesive layer) containing the compound and a support (i.e. backing layer).

Katz discloses a system and method for transdermal drug delivery. The drug delivery system of Katz contains a matrix layer and a backing or enclosure (support) (col. 3, lines 58-62). Column 5, lines 43-55 teach exemplary drugs i.e. cardioactive drugs, anti-virals, analgesics, etc. which may be incorporated in the device. Column 5, lines 56 through column 6, lines 1 and 2 teach the use of permeability enhancers such as fatty acid esters (i.e. isopropyl myristate), nonionic surfactants and fatty acid monoalkylamides and polyols (i.e. propylene glycol). It is the position of the examiner that permeability enhancers and permeability regulators are one in the same. Column 11, lines 55-60 describe the matrix containing an adhesive material which can be an acrylic.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the angiotension II receptor antagonist of '410 in the transdermal patch of Katz for the purpose of providing a percutaneous absorption preparation. The use of the angiotension II receptor antagonist in the invention of Katz is possible because Katz in column 5, lines 47-48 teaches that cardioactive drugs may be employed by the system. With respect to the claimed concentrations, the determination of particular concentrations and skin contacting area is within the skill of the ordinary worker as part of the process of normal optimization. The prior art discloses the same features in a percutaneous absorption preparation and yields the effects desired by the applicants. It is therefore the position of the examiner that the concentrations of the fatty acid ester, polyol, nonionic surfactant and skin permeability regulator, do not provide any unusual and/or unexpected results.

Response to Arguments

4. Applicant's arguments filed November 10, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the secondary reference is used to describe a transdermal device. As stated in the office action dated June 16, 2003, SmithKline Beecham discloses the use of "angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane". Katz is relied upon to teach two things (1) that drugs of the same nature as angiotension II receptor antagonist (cardioactive drugs) can be used in transdermal patches and (2) formulation of a patch that contains a skin contacting base, a drug, a skin permeability regulator (permeability enhancers) and a support. Therefore, it is the position of the examiner that the combination of SmithKline Beecham and Katz suggests the claimed invention.

Conclusion

5. Claims 4, 6, 8, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

SHELLEY A. DODSON
PRIMARY EXAMINER